

Key Marketed Products

- Neoral® (cyclosporin) builds on the established clinical utility of Sandimmun® to provide improved primary immunosuppression in organ transplant patients. Neoral® is formulated as a microemulsion, thereby providing improved absorption and less variability in dosing. Despite patent protection, generic companies have launched competing products in the United States and are expected to compete vigorously. Marketing authorizations have also been granted for generic products in Europe and elsewhere. Neoral® was launched in Japan in 2000, and these sales may partially offset reduction of sales in the United States and elsewhere.
- Sandimmun® (cyclosporin) was introduced in 1982 for the prevention of organ rejection among patients with solid organ (kidney, heart, lung and liver) transplants and bone marrow transplantation.
- Simulect® (basiliximab) is a chimeric monoclonal antibody that suppresses interleukin-driven proliferation of T-cells. Simulect® is designed to complement Neoral® in preventing acute rejection episodes in organ transplantation.

Compounds in development

- Certican® (everolimus) is a new immunosuppressant being developed for transplantation. The compound currently is in phase III clinical trials and will be used in combination with Neoral® to prevent rejection episodes in patients with kidney, lung, heart and liver transplants. Certican® is being developed in a tablet formulation.
- Myfortic™ (mycophenolate sodium) is a new immunosuppressant in development for transplantation. The compound is currently at the end of phase III clinical trials (the registration dossier has already been submitted in the EU) and is intended for use in combination with Neoral® and corticosteroids to prevent rejection episodes in patients with kidney transplants. Myfortic™ is being developed as an advanced enteric coated tablet formulation of mycophenolate.
- FTY720 is a novel immunosuppressant being developed for transplantation. The compound currently is in phase II clinical trials and is planned to be used in combination with Neoral® or Certican® to prevent rejection episodes or to enhance graft survival in patients with kidney transplants. FTY720 has a new mechanism of action altering lymphocyte homing. FTY720 is being developed in capsule, oral liquid and injectable formulations. This product has been licensed from Yoshitomi Co., Ltd. of Japan.

Dermatology

Our Dermatology portfolio covers a broad range of indications, with marketed products for the treatment of fungal infections, psoriasis and wound healing. In addition, ongoing research and development is aimed at developing new compounds and extending the clinical utility of existing compounds in the areas of allergic and inflammatory skin disease, such as atopic eczema and psoriasis. There is considerable demand for new treatments in these areas where current therapies are handicapped by limited efficacy or unacceptable side effects.

Key Marketed Products

- Elidel® (pimecrolimus cream) is a cytokine inhibitor used in the treatment of atopic eczema. The compound is a member of a new class of agents – the ascomycin macrolactams – that appear to be suitable for both short- and long-term treatment. Elidel® is now approved in the United States.
- Famvir® (famciclovir) is used in the treatment of acute herpes zoster and genital herpes, and was acquired in 2000 from SmithKline Beecham. The acquisition included global marketing rights, production rights and all intellectual property rights.

- Lamisil® (terbinafine) is used in the treatment of fungal infections of the skin, nails and scalp. Lamisil® kills the fungus, rather than simply preventing further fungal growth. An “over-the-counter” formulation is marketed by Novartis Consumer Health in many markets, including the United States.

Compounds in development

- Elidel® (pimecrolimus cream), the cytokine inhibitor approved in the United States for the treatment of atopic excema, has been in registration with the European health authorities (EMA) since June 2001. An oral form also is in development, currently in phase II.
- Lamisil® (terbinafine) is also in phase III development for tinea capitis.

Respiratory

We are committed to expanding our product range in this important disease area. A discovery and development program is aimed at providing improved therapeutic options in the treatment of asthma and chronic obstructive pulmonary disease (“COPD”), which includes chronic bronchitis and emphysema.

Recently launched/key marketed products

- Foradil® (formoterol) is a long-acting bronchodilator indicated for the treatment of asthma, approved and launched in the United States in 2001. The product was launched in its original form in 1994 outside the United States. The long-acting bronchodilator is a relatively new addition to the range of treatments for asthma, and is distinguished by its rapid onset of action (one to three minutes) and long-lasting effect from a single dose (12 hours). In addition, we are working to strengthen our position in this segment by extending the Foradil® line with an active development program. See “Compounds in development.” Foradil® is currently marketed principally in Europe in a single-dose dry powder inhaler (Aerolizer), and in certain markets as a pressurized metered dose inhaler. Foradil® received approval from the FDA in September 2001 for the indication of COPD.

Compounds in development

- DNK333 is in phase II development for the treatment of rhinitis, asthma and COPD.
- Foradil® (formoterol) is in phase III development. Ongoing research and product development is aimed at extending the clinical utility of Foradil® by registering the product for use as asthma rescue medication (“prn”—indication) and as a multi-dose dry powder inhaler.
- Xolair® (omalizumab) is an anti-IgE monoclonal antibody developed to treat allergic disease, irrespective of allergen, by normalizing serum IgE. The drug is being developed in partnership with Genentech and Tanox for the treatment of allergic asthma and seasonal allergic rhinitis and is currently in registration with the FDA and EMA. In July 2001, the FDA issued a Complete Response letter for Xolair®. The letter requests additional pre-clinical and clinical data analyses, as well as pharmacokinetic information. We will provide additional data and pending continuing discussions with the FDA, some additional trials on specific subgroups may be necessary. It is anticipated that the initial proposed label claim will likely be for adult allergic asthma. We are considering different scenarios with a conservative estimate being resubmissions ranging from 2002 to early 2003. The exact timing will be dependent on the scope of the discussions with the FDA. The new data will be submitted to the FDA and also to the EMA in the EU.

Rheumatology/Bone/Hormone Replacement Therapy (HRT)

We are a leader in the rheumatology/bone/hormone replacement therapy area with products intended to treat arthritis, osteoporosis and early menopausal symptoms, such as hot flashes, and prevent the

long-term complications of these conditions, which include cardiovascular disease and osteoporosis resulting from menopausal change. The bone and rheumatology research and development pipeline includes new compounds for the treatment of rheumatoid arthritis, osteoarthritis and bone metabolism disorders, such as osteoporosis. Research and development in HRT is primarily focused on improving the delivery of therapy via transdermal patch technology.

Key Marketed Products

- Estalis® (estradiol, norethisterone acetate transdermal system) is for the treatment of menopausal symptoms and prevention of bone loss. The compound is licensed from Aventis.
- Estraderm® TTS/MX (estradiol) are treatments for estrogen deficiency and subsequent bone loss due to menopause, whether natural or surgically induced.
- Miacalcic® (salmon calcitonin) is indicated for the prevention of progressive loss of bone mass, mainly in post-menopausal women and in elderly patients, Paget's disease and hypercalcemia. Miacalcic® is available both in an injectable form and as a nasal spray.
- Voltaren® (diclofenac) is a non-steroidal anti-inflammatory drug ("NSAID") for the treatment of inflammatory and degenerative forms of rheumatism (articular and non-articular), post-operative and post-traumatic pain and acute attacks of gout and migraines. This product faces generic competition. The brand has been extended as an over-the-counter preparation, Voltaren® Emulgel, a topical form of diclofenac for inflammation of tendons, ligaments, muscles and joints, and for localized forms of soft-tissue and degenerative rheumatism.

Compounds in development

- COX189 is an NSAID that selectively inhibits the COX-2 enzyme. The compound is in phase III clinical trials. Target indications include osteoarthritis, rheumatoid arthritis and pain.
- Zoledronic acid is being developed for several benign indications including postmenopausal osteoporosis and Paget's disease. Phase II trials in osteoporosis have shown that zoledronic acid, administered as a once per year injection, causes significant increases in bone mineral density. Phase III trials in postmenopausal osteoporosis are currently in progress.

Ophthalmics

We market products for the treatment of a number of different ophthalmic diseases. Research and development in this disease area is aimed at the discovery and development of innovative approaches to the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye.

Recently launched products

- Visudyne™ (verteporfin) is a light activated drug (photosensitizer) and is used as a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. Visudyne™ therapy uses a specially designed laser that produces the low level, non-thermal 689 nm (nanometer) light required to activate the drug. Visudyne™ has recently been launched for two new indications, pathologic myopia (in the United States and Europe) and ocular histoplasmosis syndrome (in the United States).

Key Marketed Products

- Visudyne™ (verteporfin) is commercially available in 58 countries for the treatment of predominantly classic subfoveal choroidal neovascularization (CNV) caused by age-related macular

degeneration. It is also approved in over 35 countries, including EU countries, the United States and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness).

- Zaditen® (ketotifen) ophthalmic is a new eye drop which provides fast relief of symptoms in patients suffering from ocular allergy. Zaditen® ophthalmic works through multiple mechanism of action to provide relief within minutes and a duration of action of up to 12 hours. Zaditen® provides rapid relief and long lasting control of allergy symptoms with a twice daily dosing regimen. Zaditen® is approved in more than 30 countries, including the United States (where it is marketed as Zaditor™) and the EU.

Compounds in Development

- Visudyne™ (verteporfin) is also in development for additional indications. Phase III trials are ongoing in occult age-related macular degeneration (“AMD”) and phase II trials are in progress for minimal class AMD.
- Rescula™ (unoprostone) is filed in the EU for the treatment of glaucoma.
- PKC412 is an inhibitor of Protein Kinase C, currently in development for diabetic macular edema (phase II).

Principal Markets

The world market for pharmaceuticals is concentrated in the major markets of the United States, Europe and Japan. The following table sets forth certain data relating to our principal markets.

<u>Pharmaceuticals</u>	<u>Sales 2001</u>	
	(CHF millions)	(%)
United States	8,636	43
Americas (except the United States)	1,699	8
Europe	6,122	30
Japan	2,198	11
Rest of the World	1,526	8
Total	<u>20,181</u>	<u>100</u>

Many of our products are used for chronic conditions that require patients to consume the product over long periods of time, from months to years. Accordingly, sales are not subject to material changes in seasonal demand.

Production

The key goal in our manufacturing and supply chain management program is to ensure the uninterrupted, timely and cost-effective supply of products that meet all product specifications. In order to achieve this objective, we manufacture our prescription medicines at 8 bulk chemical and 21 secondary production facilities. Major bulk chemical sites are located in Basel, Switzerland; Grimsby, United Kingdom; and Ringaskiddy, Ireland. Bulk chemical production involves the manufacture of therapeutically active compounds, mainly by chemical synthesis or by a biological process such as fermentation. Significant secondary production facilities are located in Stein, Switzerland; Suffern, New York, United States; in Sasayama, Japan and in various locations in Europe, including Italy, Spain, Germany, France, the United

Kingdom, and Turkey. Secondary production involves the manufacture of galenical forms of drug products such as tablets, capsules, liquids, ampoules, vials and creams.

During clinical trials, which can last several years, the manufacturing process is rationalized and refined. By the time clinical trials are completed and products are launched, the manufacturing processes have been extensively tested and are considered stable. However, improvements may continue throughout a product's life cycle.

Raw materials for the manufacturing process are purchased from a number of third party suppliers. Where possible, our policy is to maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers. Moreover, we monitor developments that could have an adverse effect on the supply of essential materials. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances. We also operate in a dynamic regulatory environment making supply never an absolute certainty.

Overall, prices are not volatile for materially significant raw materials.

Marketing and Distribution

We have invested significant resources in our sales and marketing organizations to achieve a competitive presence in all of the main pharmaceutical markets worldwide. In particular, the affiliates of Novartis Pharmaceuticals have a strong presence in the United States and the EU.

Products are sold to wholesale and retail drug distributors, hospitals, clinics, government agencies and managed care providers. In each market to the extent permitted by law, we deploy sales representatives to market our products and supporting medical staff to provide medical information to prescribers and healthcare purchasers. At December 31, 2001 affiliates of Novartis Pharmaceuticals had approximately 5,500 medical representatives in the US field forces, (including contract field forces) and approximately 15,800 medical representatives worldwide. Our sales and marketing reach is further extended through various agreements with promotion and marketing partners, licensees, associates and distributors.

Competition

We compete in most major markets with other global pharmaceutical companies, including Abbott Laboratories, Alcon, Allergan, American Home Products, AstraZeneca, Aventis, Bausch & Lomb, Bayer, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Pharmacia, Roche, Santen and Schering-Plough. Competition within the pharmaceutical industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

In addition to competition from ethical pharmaceutical companies, that is, companies selling patented pharmaceuticals under trademarked brand names, our pharmaceuticals business faces an increasing challenge from companies selling generic forms of Novartis products following the expiry of patent protection. In response to generic challenges that infringe upon our patents and trademarks, we vigorously defend our intellectual property rights. Where we have made meaningful improvements to existing products, we seek to extend the product range with patent-protected value-added line extensions. We focus our marketing efforts to increase brand awareness and loyalty. While competition from generic products can have a significant impact on product value, there is no guarantee that any product, even with patent protection, will remain successful if a competitor develops a new product offering significant improvements over existing therapies.

Research and Development

We are among the leaders in the pharmaceuticals industry in terms of research and development investment. In 2001, Novartis Pharmaceuticals invested approximately CHF 3.4 billion in research and

development, which represents 17% of total pharmaceuticals sales. Our Pharmaceuticals sector invested CHF 3.3 billion and CHF 2.8 billion on research and development in 2000 and 1999 respectively. There are currently 66 projects in clinical development, with 16 in Phase I and 21 in Phase II and 29 in Phase III and in registration. Products expected to be launched in 2002 from our efforts include Elidel® in Japan as well as new indications or formulations for Diovan®, Glivec®/Gleevec™, Lamisil®, Lotrel®, Ritalin® and Zometa®.

Clinical development program

Development of a new drug is a lengthy process, usually requiring 10 to 12 years from the initial research to bringing a drug to market and six to eight years from phase I clinical trials to market. Usually in phase I clinical trials, a drug is tested with about 20 to 80 normal, healthy volunteers. The tests study the drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action. In phase II clinical trials, the drug is tested in controlled studies of approximately 100 to 300 volunteer patients (*i.e.*, persons with the targeted disease) to assess the drug's effectiveness and safety, and to establish a proper dose. In phase III clinical trials, the drug is further tested on approximately 1,000 to 3,000 volunteer patients (in some cases up to 15,000 patients in total) in clinics and hospitals. Physicians monitor volunteer patients closely to determine efficacy and identify possible adverse reactions. The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug. See "—Regulation."

Initiatives to optimize the discovery and development process

We are working to be more efficient in selecting candidate drugs for development. For example, we are now better able to select the best compounds for development by having senior management focus on development projects at an early stage. Under another initiative, special teams work to develop late stage products more quickly. The goal is to improve the likelihood of therapeutic and commercial success, which should reduce development costs and decrease time to market. In several other initiatives we are improving electronic management of the clinical trial processes, including data capture and transfer, reviewing site management as well as electronic storage and archiving of study data and documents. Overall, these initiatives have the potential to substantially reduce the time between initial research and the introduction of the drug to market.

Alliances and acquisitions

Our Pharmaceuticals sector forms strategic alliances and alliance arrangements with other industry players or academic institutions in order to develop new products, acquire platform technologies and to access new markets. We license in products which complement our current product line and that are appropriate to our business strategy. A Disease Area Strategy is in place that focuses on alliances and acquisition activities for key disease areas/indications that are expected to be growth drivers in the future. Products and compounds we review for in-licensing are selected and evaluated using the same criteria as the ones used for our own internally discovered drugs.

We have long term research undertakings totaling CHF 1,480 million (US\$ 881 million) in the aggregate as of December 31, 2001. See note 29 to the consolidated financial statements. We intend to fund these expenditures from internally generated resources.

Implementation of new technologies

The completion of the human genome sequence and advances in technologies and computing are changing the way we are discovering new drugs. Functional genomics at Novartis Pharmaceuticals aims at focusing our discovery efforts on drug targets which are disease-relevant and offer potential for new

medicines which prevent or slow the progression of a disease, rather than just treat its symptoms. Genomics research groups are located in Basel, Switzerland, and New Jersey (United States) with further support from the Genomics Institute of the Novartis Research Foundation in San Diego California (United States). In total, these activities are staffed by more than 300 scientific and technical experts. This strong in-house capability is complemented by external collaborations with numerous highly regarded biotech companies and academic groups world-wide. Advances made at Novartis Pharmaceuticals and in the alliances we have with other organizations in combinatorial chemistry, ultra high throughput screening technologies, miniaturization, computational approaches, and robotics and engineering are being incorporated into our new discovery processes in order to maximize their effectiveness.

Regulation

The international pharmaceutical industry is highly regulated. National and supranational regulatory authorities administer numerous laws and regulations regarding the testing, approval, manufacturing, importing, labeling and marketing of drugs, and also review the safety and efficacy of pharmaceutical products. Further controls exist on the non-clinical and clinical development of pharmaceutical products in particular. These regulatory requirements are a major factor in determining whether a substance can be developed into a marketable product and the amount of time and expense associated with that development.

The national and supranational regulatory authorities, especially in the United States, the EU and Japan, have high standards of technical evaluation. The introduction of new pharmaceutical products generally entails a lengthy approval process. Of particular importance is the requirement in all major countries that products be authorized or registered prior to marketing, and that such authorization or registration be subsequently maintained. The regulatory process requires increased testing and documentation for clearance of new drugs, with a corresponding increase in the expense of product introduction.

To register a pharmaceutical product, a registration dossier containing evidence establishing the quality, safety and efficacy of the product must be submitted to regulatory authorities. Generally, a therapeutic product must be registered in each country in which it will be sold. In all jurisdictions, the submission of an application to a regulatory authority does not guarantee that approval to market the product will be granted. Although the criteria for the registration of therapeutic drugs are similar in most countries, the formal structure of the necessary registration documents varies significantly from jurisdiction to jurisdiction. It is possible that a drug can be registered and marketed in one country while the registration authority in a neighboring country may, prior to registration, request additional information from the pharmaceutical company or even reject the product.

The registration process generally takes between six months and several years, depending on the jurisdiction, the quality of the data submitted, the efficiency of the registration authority's procedures and the nature of the product. Many countries provide for accelerated processing of registration applications for innovative products of particular therapeutic interest. In recent years, intensive efforts have been made among the United States, the EU and Japan to harmonize registration requirements in order to achieve shorter development and registration times for medical products. However, the requirement in many countries to negotiate selling prices or reimbursement levels with government regulators can substantially extend the time until final marketing approval is granted.

The following provides a summary of the regulatory process in the principal markets served by affiliates of Novartis Pharmaceuticals:

United States

In the United States, applications for drug registration are submitted to and reviewed by the FDA. The FDA regulates the testing, approval, manufacturing, and labeling of pharmaceutical products intended for commercialization in the United States, as well as the monitoring of all pharmaceutical products

currently on the US market. The pharmaceutical development and registration process is typically intensive, lengthy and rigorous. A new drug application (“NDA”) or a Biologics License Application (“BLA”) for biologic products, (hereafter referred to synonymously with NDA) is filed with the FDA if the data sufficiently demonstrate the drug’s quality, safety and efficacy. The NDA must contain all the scientific information that has been gathered and typically covers all patients tested in clinical trials. A supplemental new drug application (“sNDA”) must be filed for a line extension of, or new indications for, a previously registered drug.

Once the FDA approves the NDA/sNDA, the new pharmaceutical becomes available for physicians to prescribe. Thereafter, the drug owner must submit periodic reports to the FDA, including any cases of adverse reactions. For some medications, the FDA requires additional post-approval studies (phase IV) to evaluate long-term effects or to gather information on the use of the product under special conditions. The FDA also requires compliance with standards relating to laboratory, clinical and manufacturing practices.

European Union

In the EU, there are two main procedures for application for marketing authorization, namely the Centralized Procedure and the Mutual Recognition Procedure. In the Centralized Procedure, applications are made to the European Medical Evaluations Agency (“EMA”) for an authorization which is valid across all EU member-states. The Centralized Procedure is mandatory for all biotechnology products and optional for other new chemical compounds or innovative medicinal products. In the Mutual Recognition Procedure, a first authorization is granted by a single EU member-state. Subsequently, mutual recognition of this first authorization is sought from the remaining EU member-states or subset thereof. National authorizations are only possible for products intended for commercialization in a single EU member-state only, or for line extensions to existing national product licenses.

Japan

In Japan, applications for new products are made through the Pharmaceutical and Medical Devices Evaluation Center (“PMDEC”). After a data reliability survey and a Good Clinical Practice inspection are carried out by the Organization for Pharmaceutical Safety and Research (“OPSR”), a team evaluation is passed to the Central Pharmaceuticals Affairs Council (“CPAC”), whose special members, committees and executive committees provide a report back to the PMDEC. After a further team evaluation, a report is provided to the Ministry of Health, Labor and Welfare (“MHLW”), which makes a final determination for approval and refers this to the CPAC which then advises the MHLW on final approvability. Drug manufacturing or import license approval is issued by the local prefecture government.

Price Controls

In many of the markets where we operate, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

In the United States, debate over the reform of the healthcare system has resulted in an increased focus on pricing. Although there are currently no government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under healthcare programs. In the absence of new government regulation, managed care has become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. In addition, the current national debate over Medicare reform could increase pricing pressures. If Medicare reform results in the provision of outpatient pharmaceutical coverage for beneficiaries, the US government could use its enormous purchasing power to demand discounts from pharmaceutical companies thereby creating *de facto* price controls on prescription drugs. On the other hand, Medicare drug reimbursement legislation may increase the volume of pharmaceutical drug purchases, offsetting, at least in part, potential price discounts. As a result, we expect that pressures on pricing and operating results will continue and may increase.

In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the UK, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries, cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

In Japan, the National Health Ministry biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions. The Japanese government is planning a healthcare reform initiative to be implemented in 2002 and it is expected that the pharmaceutical pricing system will be one of the issues reviewed. The key issues are the evaluation of innovative products and the pricing of older products, including the biannual reduction of reimbursement prices adjusted for actual discounts given. The previously proposed reference price system has been abandoned by the government.

Intellectual Property

We attach great importance to patents, trademarks, and know-how in order to protect our investment in research and development, manufacturing and marketing. It is the policy of the Group to seek the broadest possible protection for significant product developments in all major markets. Patents may cover products *per se*, product formulations, processes, intermediate products and product uses.

Protection for individual products extends for varying periods depending on the date on which the patent application was granted and the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage. In most industrial countries, patent protection exists for new active substances and formulations, as well as for new indications and production processes. We monitor our competitors and vigorously challenge patent and trademark infringements of our intellectual property.

Patent protection is no longer available in several major markets for the active ingredients used in a number of our Pharmaceutical sector's leading products:

- Patent protection exists for the Neoral® microemulsion formulation and other cyclosporin formulations through 2009 and beyond in major markets. Despite this protection generic cyclosporin products competing with Neoral® have entered the transplantation market in the United States, Germany and elsewhere. Patent infringement proceedings have been filed and are pending.
- Our patent protection for Aredia® is limited. One generic version of Aredia® was launched in the United States in December 2001. Others are tentatively approved for marketing by the FDA and are expected to be launched in approximately May 2002. Generic products to Aredia® are on sale in Canada and elsewhere. We have a next generation drug, Zometa®, which was approved and launched in the United States in 2001 and is also launched in other key markets for its first indication. Patent protection will expire in major markets for the key product Sandostatin®. The basic octreotide substance patents expire in late 2002 in the United States, and Japan, and from 2003 to 2009 in major EU countries. However, protection extending to 2010 (and 2013 and beyond in the United States) continues in major markets for Sandostatin® LAR, which represents a significant and growing proportion of Novartis Pharmaceuticals octreotide sales.
- The basic benazepril substance patent for Cibacen®/Lotensin® will expire in Japan in 2002 and in the United States in 2003, but will remain in place in major markets in the EU. Lotrel®, the fast growing combination of benazepril with amlodipine, on the other hand, is patented in the United

States till 2017 and is expected to at least partially offset potential generic erosion on Cibacen®/Lotensin® sales. Lotrel® contributes a growing proportion of Cibacen®/Lotensin® group sales.

- Voltaren® is another major Novartis product facing generic competition.

The loss of patent protection can have a significant impact on Novartis Pharmaceuticals, and we work to offset these negative effects by developing and patenting inventions that result in process and product enhancements and by positioning many of our products in specific market niches. However, there can be no assurance that this strategy will be effective in the future to extend competitive advantage, or that we will be able to avoid substantial adverse effects from future patent expirations.

GENERICIS

The business of Generics is conducted by a number of affiliated companies throughout the world and provides off-patent pharmaceutical products and substances. The affiliates of Generics compete in two principal product segments: finished dosage forms ("Generic Pharmaceuticals Business") and active pharmaceutical ingredients and their intermediates ("Industrial Business"). In the Generics Pharmaceuticals Business, finished dosage forms are sold to pharmacies, hospitals and other healthcare outlets, while in the Industrial Business, active ingredients and their intermediates for pharmaceutical and biotechnological substances are sold to industrial customers.

As of December 31, 2001, the affiliates comprising Generics employed 7,230 people. Generics products are sold in over 140 countries throughout the world. In 2001, the affiliates comprising Generics had CHF 2,433 million in sales, which represented 7% of the Group's sales.

In 2001, Generics sales grew by more than 26% in local currencies. The business year was characterized by the integration of companies acquired in 2000 and 2001 and high volume growth in both the Industrial and Generic Pharmaceuticals Businesses. However, continued price pressure, especially in the Generic Pharmaceuticals Business, partially offset the very dynamic sales growth and thereby increased pressure on operating income development.

In the United States, double digit sales growth was achieved despite continued decreasing prices. Improved performance is attributable to significant improvements at Geneva Pharmaceuticals, Inc., the integration of Apothecon's former unbranded generics business (acquired in 2000), strong volume growth and successful launches of important finished dosage form pharmaceuticals, i.e. fluoxetine, the generic form of the blockbuster anti-depressant Prozac®, for which Geneva held a 6-months-exclusivity in the United States for the ten milligram capsule formulation of this medication. With the addition of the former Apothecon, we have become one of the top four competitors in the US generic pharmaceuticals business.

The globally active Biochemie GmbH ("Biochemie"), headquartered in Kundl/Austria, achieved considerable sales growth (5%) in 2001, providing products in both the Industrial Business segment as well as Generic Pharmaceuticals Business segment. Main growth drivers were the generic version of the antibiotic amoxicillin/clavulanic acid as well as active ingredients and intermediates for penicillins and cephalosporines.

In 2001, our Industrial Generics Business succeeded in realizing considerable volume growth in active ingredients (penicillins, cephalosporin and intermediates). In addition, due to the shift to high-value-compounds for cephalosporin antibiotics and additional long-term contracts with major pharmaceutical and biotech companies, we achieved improved performance in 2001 in our Industrial Generics Business.

Key Marketed Products

Approximately 67% of the sales of Generics are derived from our Generic Pharmaceuticals Business and approximately 33% of sales are derived from our Industrial Business.

Key marketed product areas are antibiotics (such as penicillins, cephalosporins, macrolides and medicines for the treatment of tuberculosis), central nervous system drugs, cardiovascular drugs, alimentary tract preparations and hormonal tract preparations.

Recently launched products

- A ten miligram capsule formulation of fluoxetine (the generic form of Prozac® from Eli Lilly); an essential treatment for depression.
- A generic combination amoxicillin/clavulanic acid under the brand names Curam® and Clavamox®. This antibiotic combination is an important treatment for bacterial infections.
- The antibiotics Roxythromycin AZU® and Ciprofloxacin® AZU®, Felodipin AZU® for heart disease, and Loratadin for allergies.

In 2001, Generics affiliate Biochemie began manufacturing enzymatically produced 7-ACA in Frankfurt, Germany as a complement to the manufacture of this product at its Austrian plant (which uses chemical methods in production). Biochemie is the world leader in the production of this key intermediate for cephalosporin antibiotics. Biochemie also entered into several new alliances with several international pharmaceutical companies for the manufacture of specific custom-made intermediates for cephalosporine antibiotics.

In Spain, a Biochemie affiliate began manufacturing active ingredients for semisynthetic macrolides. This extension is a major step in our strategy to diversify our anti-infectives portfolio and to become a leading player in this market segment.

Principal Markets

The principal markets of Generics are the two largest generics markets in the world: the United States and Europe. The following table sets forth the aggregate 2001 sales of Generics by region:

<u>Generics</u>	<u>Sales 2001</u>	
	(CHF millions)	(%)
United States	789	32
Americas (except the United States)	209	9
Europe	1,022	42
Japan	53	2
Rest of the World	360	15
Total	<u>2,433</u>	<u>100</u>

In 2001, sales growth in the United States (39%) was mainly due to the successful integration of the product range of Apothecon's unbranded generics business and the launch of generic fluoxetine in the second half of 2001.

Sales growth in Latin America (34%) was due to the continuous development of the Mexican operation and the market entry in Argentina through the acquisition of Labinca SA. Novartis Generics intends to improve its market share through continued sales growth in Mexico and Venezuela, in addition to the new market entry in Argentina and a greenfield market entry in Brazil. Success in both Argentina and Brazil are dependent on those countries overcoming present financial difficulties.

Sales growth in Western-Europe (21%) was due to a greenfield market entry strategy in Scandinavian countries, Belgium and Greece; the acquisition of Lagap Pharmaceuticals in the United Kingdom and the

acquisition of the BASF generics business in several European countries, including France and Italy. In 2001 Germany remained the most important generics market in Europe. Due to changes in legislation the pharmaceutical markets in France and Italy opened for generic medicines.

Sales development in Asia/Pacific/Africa remained at a high level (6%).

Production

For finished dosage forms, the principal production facilities are located in Broomfield, Colorado (United States); Dayton, New Jersey (United States); Gerlingen, Germany; Kundl, Austria; Jakarta, Indonesia; Spartan, South Africa; Tongi, Bangladesh; and Buenos Aires, Argentina. Plants for active pharmaceutical ingredients are located in Kundl and Schafhausen, Austria; Frankfurt, Germany; Rovereto, Italy; Les Franqueses, Spain; Jakarta, Indonesia, and Turbhe/Mumbai, India.

Agricultural raw materials such as flours and sugars are sourced from multiple suppliers based in both the United States and the EU. Chemicals and other raw materials are globally sourced with a focus on United States and EU-based suppliers. Raw materials are priced for the most part on world markets and price fluctuations are partially avoided through the use of long-term supply contracts. In addition, e-procurement methods are being initiated by several Generics affiliates to further strengthen their purchasing productivity.

Biotech substances like enzymes for detergents, and many of the active pharmaceutical ingredients, like penicillins, are produced using modern bio-technological methods. Primary production methods include fermentation processes, chemical syntheses and physical production methods, such as sterile precipitation. The fermentation process uses genetically modified micro-organisms, such as e-coli bacteria and molds. Other new manufacturing processes are constantly being developed.

Marketing and Distribution

In our Generics Pharmaceuticals Business, we have a broad portfolio of off-patent medicines that are sold to pharmacies, hospitals, and other healthcare outlets. Depending on the structure of local markets, these markets are serviced either by the field service team of the local Generics affiliate or by well established partners or joint venture associates.

In our Industrial Business, active pharmaceutical ingredients and biotech substances are sold to manufacturers in the pharmaceutical industry.

In response to rising healthcare costs, many governments and private medical care providers, such as HMOs, have instituted reimbursement schemes that favor the substitution of generic pharmaceuticals for more expensive brand-name pharmaceuticals. In the United States, generic substitution statutes have been enacted by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug instead of an original ethical drug. In Europe, use of generic drugs is growing, but penetration rates are still below those reached in the United States because, in some EU countries, reimbursement practices do not create an efficient incentive for generic substitution.

Competition

In our Generics Pharmaceuticals Business, key competitors in the United States are Barr, Mylan, Teva/Novopharm/Copley, and Watson/Schein. In Europe, key competitors are Hexal, Ratiopharm, Stada Teva, Merck Generics and Alparma.

In our Industrial Business, the main competitors for active pharmaceutical ingredients are Antibioticos and DSM-Anti-Infectives (both headquartered in the EU). East-Asian manufacturers are increasingly competing in selected markets.

The market for generic products is characterized by increasing demand for high-quality pharmaceuticals which can be produced at lower costs due to minimized initial research and development

investments. Increasing pressure on healthcare expenditures and numerous patent expirations have created a favorable market environment for the generics industry. This positive market trend, however, brings increased competition within the generics industry, leading to ongoing price pressure on generic pharmaceuticals.

Research and Development

There is intensive development work required in order to demonstrate the bioequivalency of a generic drug to the original ethical drug. Nevertheless, research and development costs associated with generic drugs are much lower than those of their original counterparts. Thus, off-patent drugs can be offered for sale at prices much lower than those of patented drugs, which must recoup substantial basic research and development costs through higher prices over the life of the product's patent.

Currently, the affiliates of Generics employ approximately 700 researchers who explore alternative routes for the manufacture of known compounds and who aim to develop innovative forms of generic drugs. Most of these researchers are based at facilities in Kundl, Austria; Dayton, New Jersey; and Mumbai, India. Generics invested CHF 169 million, CHF 170 million, and CHF 126 million in research and development related to generic products in 2001, 2000, and 1999, respectively.

In Vienna, Austria, we opened a new research center with a staff of 50 where new active substances are being developed for use as antibiotics.

Regulation

The Waxman-Hatch Act in the United States (and similar legislation in some other countries) eliminated the repetition of extensive clinical trials for generic drugs so long as they could be shown to be of identical quality and purity and to be biologically equivalent to the original ethical drug.

In the EU, although certain new drugs are subject to a Centralized Registration Procedure, most applications for marketing approval still need to be filed on the national level. However, in an effort to streamline the registration process, a national registration may be used as the basis for EU marketing approval under the Mutual Recognition Procedure. See "Pharmaceuticals—Regulation."

Intellectual Property

Wherever possible our products are protected by trademarks and patents. Patents may cover products, product formulations, processes, intermediate products or product uses. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

CONSUMER HEALTH

The business of Consumer Health is conducted by a number of affiliated companies throughout the world, operating in three business units: "Over-the-Counter" (OTC) self-medication, Health and Functional Nutrition (including Infant and Baby products), and Medical Nutrition. Through these units, we develop, manufacture and market a wide range of health and medical nutrition products and a portfolio self-medication brands. In 2001, the affiliates of Consumer Health employed 12,824 people and had CHF 6,675 million in sales, which represented 21% of the Group's sales. Headquartered in Nyon, Switzerland, Novartis Consumer Health affiliates operate in 52 countries worldwide.

On February 4, 2002, we announced our intention to divest certain parts of the Health and Functional Food business part of Health and Functional Nutrition before the year end 2002. This reorganization will better meet customer needs and strengthen growth initiatives, furthering the Group's strategic focus on healthcare with pharmaceuticals at the core. Among the brands to be divested include Céreal®, Gerblé®, Ovaltine®, Ovalmatine®, Isotar®, Gerlinea®, and Pesofarma®. We intend to retain the Infant and Baby Food Business, including Gerber®.

The present form of Consumer Health was created on January 1, 1999 by merging the Group's OTC and nutrition businesses. At that time non-core brands were divested. All significant restructuring and integration activities relating to the merger have been successfully completed.

The three business units: OTC, Health and Functional Nutrition and Medical Nutrition, contributed to sales as follows:

<u>Consumer Health</u>	<u>Sales 2001</u>	<u>Sales 2000⁽¹⁾</u>	<u>Sales 2000</u>	<u>Sales 1999</u>
	(%)	(%)	(%)	(%)
OTC	40.0	40.2	39.1	40.2
Health and Functional Nutrition	49.7	50.1	51.0	49.9
Medical Nutrition	10.3	9.7	9.9	9.9
Total	<u>100.0</u>	<u>100.0</u>	<u>100.0</u>	<u>100.0</u>

⁽¹⁾ Historical data have been restated to reflect the transfer of certain products from Novartis Pharmaceuticals.

Key Marketed Products

OTC

Our OTC business provides products for the treatment and prevention of common medical conditions and ailments to enhance people's overall health and well being. Our OTC business is ranked as a global top 5 self-medication business with strong positions in Europe and North America. The current product portfolio includes 40 key marketed brands.

The main product categories are cough, cold and allergy treatments, gastrointestinal treatments, dermatological treatments, analgesics, vitamins, minerals and supplements, venous disorder treatments and smoking cessation treatment. The major OTC brands are:

<u>Key brands</u>	<u>Market/segment</u>
Voltaren® Emulgel	Topical Muscle Pain
Nicotinell/Habitrol®	Smoking cessation
Lamisil®AT Cream	Athlete's foot treatment
Sandoz®	Minerals
Triaminic®	Pediatric cough & cold
Maalox®	Antacid
Otrivin®	Nasal decongestant
NeoCitran®, TheraFlu® & Triaminic®	Cold remedies and flu
Venoruton®	Venous disorders
Tavegyl®/Tavist®	Cough, cold, allergy

Life-cycle management has become an important tool following the transfer of two key brands from Pharmaceuticals: Voltaren® Emulgel and Lamisil®AT Cream. In the United States, Lamisil®AT Cream rapidly built a strong OTC market share following its switch from prescription only to OTC status by providing consumers with a new standard in efficacy for the common problem of athlete's foot. We

followed this success with a number of innovative line extensions including the introduction of the cream in other global markets during 2001.

Voltaren® Emulgel, a topical analgesic for muscular pain, has also enjoyed significant growth when it switched to OTC from prescription-only status. In the EU, a winning marketing campaign, first introduced in Germany for Voltaren® Schmerzgel, has now been rolled out to numerous other markets with similar success. The prescription to OTC switch of this brand is now ranked in Europe as the second most successful switch in history of the OTC industry.

In 2001, we introduced new improved formulations for Maalox® liquid antacid in the United States and Quick Dissolves® chewable tablets for the Sandoz® mineral line in Europe.

At the beginning of the third quarter of 2001, Pharmaceuticals transferred to Consumer Health the antiviral Denavir® for the US market, and it is currently sold under prescription.

Health and Functional Nutrition

The Health and Functional Nutrition Business encompasses foods designed to serve the particular nutritional needs of target groups including infants, athletes, and the elderly. Products include baby foods, consumer products such as sports drinks, slimming aids and functional health foods. On February 4, 2002, we announced our intention to divest the Health and Functional Food portion of this business before the year-end 2002. The Infant and Baby Food business, including Gerber®, will be retained.

In 2001, the Health and Functional Nutrition business refocused advertising and promotion investments through innovative programs in the core-based businesses: Gerber®, Ovaltine®/Ovomaltine®, Isostar®, Céreal®/Gerblé® and Gerlinea®.

We have mutually agreed with our joint venture partner, The Quaker Oats Company, not to proceed further with our alliance known as Altus Food Company.

The major brands and product groups in Health and Functional Nutrition are:

<u>Key Brands</u>	<u>Product groups</u>	<u>Main markets</u>
Gerber®, Galactina®, Tender Harvest®, Graduates®	Baby food	US, Latin America, Europe, Asia
Céreal®, Gerblé®	Health foods ⁽¹⁾	Europe
Ovaltine®/Ovomaltine®	Food drinks ⁽¹⁾	US, Europe, Asia
Isostar®	Sports nutrition ⁽¹⁾	Europe
Modifast®, Gerlinea®, Pesofarma®	Slimming ⁽¹⁾	Europe

⁽¹⁾ Proposed to be divested as part of Health and Functional Foods.

Gerber® continued to build on its position as a leader in infant feeding and care with a number of innovations in 2001. Gerber® is the first company to deliver single-serve plastic packages, ideal for out-of-home feeding. Gerber® now offers all juices and top selling fruit purees in plastic containers. The premium/organic Tender Harvest® line was extended to include 1st food segment for the baby's progression to cereal, and 3rd food segment for older babies learning how to chew and mash foods.

Within the Gerber® Care/Wellness line, new hypoallergenic products such as foaming shampoo, baby powders and oils, moisturizers (for both face and body) were launched in 2001. In addition, an advanced line of pacifier (Gentleflex®) and nipple products (New Traditions®) provides for a smoother transition

from breastfeeding to bottle-feeding. Lastly, a new highly absorbent variety of pads for nursing mothers are now available.

The conversion of glass containers to plastic will continue in 2002 and beyond to make products more convenient for on-the-go parents. In addition, innovative multi-compartment “dinners” offering greater convenience are being developed for a 2002 launch.

In Health Food, the focus for 2002 will continue to be on the high growth categories of Sports Nutrition and Slimming, driven by Isostar®, which was launched in 2001 in a new 500 milliliter PET bottle in selected European markets and through an improved range of slimming products offering more complete meal replacement.

Medical Nutrition

Our Medical Nutrition business focuses on the nutritional needs of people with serious (often chronic) conditions as well as hospitalized or convalescing patients. Our product portfolio ranges from enteral tube feeds and devices to oral supplements. Our main brands and product groups in this area include:

<u>Key brands</u>	<u>Product groups</u>
Isosource®, Novasource®, IMPACT®, Vivonex®	Tube feeds
Isosource®, Novasource®, IMPACT®, Resource® Professional®	Clinical supplements
Resource®	Health Care Food Service
Compat®	Medical devices

45% of our 2001 incremental revenues have been generated by products launched in 2001, principally for gastro-intestinal and diabetes indications, under the brands Resource®, Isosource® and Novasource®.

We expect that future growth will be generated by increased penetration in the Care/Hospital & Home Health Care trade channels and continued development of products that help normalize blood glucose levels, reduce the risk of infections or improve tissue healing.

Principal Markets

In 2001, Consumer Health realised the majority of its sales in its two principal markets: the United States and the EU. The following table sets out our 2001 sales by geographic region.

<u>Consumer Health</u>	<u>Sales 2001</u>	
	(CHF millions)	(%)
United States	3,283	49
Americas (except the United States)	689	10
Europe	2,173	33
Rest of World	530	8
Total	<u>6,675</u>	<u>100</u>

Apart from the cough and cold business which represents 25% of OTC sales, Consumer Health sales are not characterized by seasonal fluctuations. A number of our OTC brands currently benefit from reimbursable status by governments and other third party payers in European and other global markets.

Production

Major production sites ranked by importance are in the United States, Switzerland, Mexico, France, Germany, Puerto Rico, Poland, Costa Rica and China. In 2001, a major consolidation of the Ovomaltine® production capacity in Europe was announced, leading to the closure of the United Kingdom production facility.

The goals of our supply chain strategy include a high efficiency, low cost structure and the mitigation of risks through multiple production sources. Regional sites serve specific markets but are also capable of providing support as needed to other regions in the event of supply disruption. In addition, we source a large quantity of OTC products from factories owned and operated by the affiliates of Pharmaceuticals thereby providing flexibility and predictable sources of supply in the event of capacity constraints or other potential disruptions to ongoing supply.

Raw materials for the manufacturing process are purchased from a number of our affiliates and third party suppliers. For the most part, the products and services we procure are not proprietary and are available from a number of suppliers. We often “single-source” supplies, but we have a policy of having at least a second approved and validated supplier registered for most key materials so that substitution is possible. Where practical and beneficial, we have long-term contracts in place on key production inputs. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials. While we have not experienced material supply interruptions caused by vendors in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances. Additionally, we operate in a dynamic regulatory environment, making supply never an absolute certainty.

The non-proprietary nature of most of our raw materials allows us to benefit from attractive supply prices. Although we face volatility in the commodity markets just like any similarly situated company, prices for our unique raw materials are not overly volatile.

Marketing and Distribution

We aim to be a leading global participant in fulfilling the needs of patients and consumers for health and medical nutrition and self-medication healthcare. Strong brands, science-based products and in-house marketing and sales organisations are key strengths that allow the business to achieve this objective. We distribute our products through various channels, such as hospitals, nursing homes, pharmacies, food, drug and mass retail outlets.

Competition

The fundamental trends driving the growth of our OTC business are increasing pressures on government health funding, changing consumer attitudes towards personal well being, the rise of a self-care mentality among consumers and successful switches of prescription products to OTC status. Our principal competitors in this highly competitive market segment are major international corporations with substantial financial and other resources, including American Home Products, Aventis, Bayer, GlaxoSmithKline, Johnson & Johnson, Procter & Gamble, Roche and Pfizer.

In Health and Functional Nutrition the main competitors are multinational food companies. In the slimming and functional health foods segment, the market is very fragmented and consists of a number of competitors. In the Baby Food business, where the market is relatively flat as the number of births has stayed around 0–2% growth per annum, competitors in the United States are Heinz and Beechnut. In the

baby care and wellness portion of the market the main competition in the United States comes from Johnson & Johnson and Playtex.

Major competitors in the Medical Nutrition market are Abbott Ross, Fresenius, Mead Johnson, Nestlé, and Numico.

Research and Development

In OTC, the focus of research and development activities is primarily on cough, cold, allergy, gastrointestinal, minerals, analgesics, dermatology, cardiovascular risk reduction (through smoking cessation programs) and management of venous diseases. Consumer Health also works closely with Pharmaceuticals to evaluate appropriate products that can be switched from prescription to OTC status. The development of line extensions to leverage the brand equities is also of high importance. These extensions can take the form of new flavor improvements or the introduction of novel galenic forms.

Currently, Consumer Health has a large number of research and development projects in progress. While the majority of these are in the OTC business unit, there is also significant activity within the Medical Nutrition and Health and Functional Nutrition business units. The affiliates of Consumer Health employ a dedicated research and development team of over 450 employees based mainly in the United States and Switzerland. We have devoted CHF 181 million, CHF 186 million and CHF 167 million to research and development relating to our Consumer Health products in 2001, 2000 and 1999 respectively.

Consumer Health continuously monitors product safety and works to make certain that the benefits outweigh the risks of all products within its portfolio.

Regulation

For OTC products, the regulatory process for bringing a product to market consists of preparing and filing a detailed dossier with the appropriate national or international registration authority and obtaining approval in the United States or registration in the EU and the rest of the world.

The FDA regulates approval of OTC products in the United States via the US Food Drug and Cosmetic Act. There are two legal bases for marketing an OTC product, either through an approved New Drug Application (NDA) to establish a product's safety and effectiveness for its intended use, or if the active ingredient is generally recognised as safe and effective, through a regulatory process known as the OTC Review.

In the OTC Review, the FDA specifies in a series of monographs (by pharmacological category) the conditions under which certain active ingredients would generally be recognised as safe and effective for their intended use (*i.e.* to change from prescription status to OTC status). Compliance with the published monograph, therefore, permits marketing without an NDA and its formal approval process. The monograph process is unique to the US market.

The prescription-to-OTC switching process exists in most countries around the world and varies from country to country.

Foodstuffs are highly regulated in order to protect public health and to prevent misleading of consumers. The following matters generally are subject to international and national food regulations: development, manufacturing, packaging, quality (food standards, ingredients), safety, labeling and advertising of foods.

Food manufacturers are responsible for product safety, not misleading consumers and complying with national food laws. Many technical aspects of food regulation are not harmonized among countries. New food ingredients and new product claims generally require special approvals from national food authorities. This applies for new medical foods, dietetic foods such as sports foods and slimming foods and some new baby foods.

In the United States, the safety of new food ingredients is assessed by the FDA. In the EU, the safety of new food ingredients is assessed with the Novel Food Process. An EU member-state makes the initial risk assessment, which may then be challenged afterwards by the EU Commission and the other EU member-states. In Japan, Foods for Special Health Use are put on the market after approval has been obtained from the Ministry of Health, Labor and Welfare. This includes approval of product quality, ingredients and product claims.

Intellectual Property

Our Consumer Health businesses are brand-oriented and, therefore, we consider our trademarks to be of utmost value. Trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative.

Wherever possible our products are protected by patents. Patents may cover products, product formulations, processes, intermediate products or product uses. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

CIBA VISION

The business of CIBA Vision is conducted by a number of affiliated companies in more than 70 countries. CIBA Vision is a world leader in the research, development and manufacturing of eye care products, namely soft contact lenses, lens care products, and ophthalmic surgical products. As of December 31, 2001, the affiliates of CIBA Vision employed more than 6,700 people. In 2001, CIBA Vision had sales of CHF 1,787 million, which represented 6% of the Group's sales.

CIBA Vision completed the acquisition of Wesley Jessen VisionCare, Inc., a leading provider of specialty contact lenses in the United States, in October 2000.

On January 1, 2001, CIBA Vision's Ophthalmic Pharmaceuticals Business Unit became part of the Novartis Pharmaceuticals sector in a reorganization.

Recently Launched Products

- Focus® NIGHT & DAY™ is the first high-oxygen permeable continuous wear contact lens that can be worn for up to 30 days and nights continuously. The product was launched in the United States in November 2001. The lens was first launched in 1999 and is now available in more than 40 countries.
- CIBA Vision launched Focus® DAILIES Progressives in the United States and Canada in June 2001. It is the first daily disposable contact lens in the world to correct presbyopia. Focus® DAILIES® Progressives are also available in Europe and Hong Kong.
- AOSept Clear Care, an enhanced formulation of our leading hydrogen peroxide disinfectant, was launched in the United States in June 2001. It is the first one-bottle, no rub lens care solution with no added preservatives in the United States.
- SOLO-care® Plus, an enhanced formulation of our one-bottle lens disinfection system, received the CE mark in April 2001 and FDA approval in December 2001. The product offers a one-bottle, no rub, no rinse cleaning and disinfection system.
- CIBA Vision introduced several innovative intraocular lenses:
 - In 2000 the CE Mark was obtained for the PRL (Phakic Refractive Lens), a foldable posterior chamber phakic refractive lens designed to float on a patient's natural lens and to self-center behind the iris. FDA clinical trials are ongoing in the United States.

- In 2001 the CV 232, the only pre-rolled intraocular lens in the world, was introduced. This product allows surgeons to insert the lens through an even smaller incision than before. It is used to restore vision in patients with cataracts.
- Vivarte™, is the first and only foldable anterior chamber phakic refractive lens. The three-point design increases the stability of the lens and is designed to provide optimum safety. Vivarte™ will be launched in Europe in early 2002.

Key Marketed Products

The table below sets out the key marketed products in each of CIBA Vision's three principal product segments:

Main Products	Description
Contact Lenses	
Focus®Toric	Corrects astigmatism
Focus®Monthly	Replaced monthly
Focus®1-2 Week	Replaced every one to two weeks
Focus®1-2 Week SoftColors	Replaced every one to two weeks; enhances the color of light eyes
Focus®DAILIES®	One-day disposable
Focus®Progressives	Corrects presbyopia
Focus®NIGHT&DAY™	Extended wear for up to 30 days and nights continuous wear
Focus® DAILIES Progressives	One day disposable to correct presbyopia
DuraSoft 3 Colors	Conventional cosmetic tinted lenses
FreshLook® Colorblends	Opaque lenses that blend three colors on one lens creating a more natural looking cosmetic tinted lens for dark or light eyes
Precision UV®	First Disposable lens with ultraviolet light protection
WildEyes®	Novelty lenses
Illusions® Opaque	Conventional lenses for changing the color of dark eyes
Cibasoft®	Conventional lenses with handling tint
Cibasoft® Softcolours®	Conventional lenses for enhancing the color of light eyes

Main Products	Description
Lens Care Products	
AOSept®	Hydrogen peroxide disinfectant system
AOSept® Clear Care/AOSept Plus	An enhanced formulation of our leading hydrogen peroxide disinfectant; the first one-bottle, no rub lens care solution with no added preservatives in the United States
SOLO-care®	One bottle lens disinfectant system
SOLO-care® Plus	An enhanced formulation of our one-bottle lens disinfection system; offers a one-bottle, no rub, no rinse cleaning and disinfection system
QuickCARE™/InstaCARE	Five-minute disinfectant system
Pure Eyes®	Two-bottle hydrogen peroxide system
Focus® Lens Drops	For lubricating contact lenses
Ophthalmic Surgical	
MemoryLens®	Pre-rolled, foldable intra-ocular lens, used in a surgical procedure to restore vision in people with cataracts
PRL (Phakic Refractive Lens)	The first and only foldable posterior chamber phakic refractive lens designed to float on a patient's natural lens and to self-center behind the iris
Vivarte™	The first and only foldable anterior chamber phakic refractive lens
Bioinsulated® Punctum Plus	Provides relief from severe dry eye symptoms
UniVisc®	Viscoelastic solution
Ophthalmal™ and Ophthalmal Plus™	Viscoelastic solution offered outside the United States
Sapphire Microsurgical Knives and Phaco Blades	Surgical instruments

Products in Development

CIBA Vision intends to expand its product portfolio through both its own dedicated research and development resources as well as the acquisition of new and innovative technologies. Product development is focused on contact lenses as well as ophthalmic surgical products and involves the creation and development of entirely new product offerings in these markets as well as line extensions of current products. The acquisition of Wesley Jessen VisionCare, in October 2000 included several exciting technologies and CIBA Vision anticipates incorporating these technologies into other contact lens products in its pipeline.

Principal Markets

Our principal markets, in terms of 2001 sales, were North America (United States and Canada), Japan and Europe. Sales are not subject to seasonality. The following table sets forth 2001 sales for CIBA Vision by region:

<u>CIBA Vision</u>	<u>Sales 2001</u>	
	(CHF millions)	(%)
United States:	760	43
Americas (except the United States)	98	5
Europe	543	30
Japan	259	15
Rest of the World	127	7
Total	<u>1,787</u>	<u>100</u>

Production

CIBA Vision has seven major manufacturing sites: Grosswaldstadt, Germany (contact lenses); Amwiler Facility, Atlanta, Georgia, United States (contact lenses); Johns Creek Facility, Atlanta, Georgia, United States (contact lenses); Batam, Indonesia (contact lenses); Mississauga, Canada (lens care products); Cidra, Puerto Rico (intra-ocular lenses and contact lenses); and Des Plaines, Illinois, United States (contact lenses). We purchase basic chemical commodity raw materials for our lens products from industrial vendors. These raw materials are then reformulated into the monomers and polymers required to produce contact lenses. Polymer chemistry is one of the innovative elements in our contact lens products. The technology to produce the polymers and monomers is stable and well-defined.

We enter into long-term supply contracts (generally over one to two years) with industrial raw material vendors, which limits volatility. In addition, most raw materials are basic chemical commodities and multiple suppliers are available. Certain lens products use proprietary chemicals that are produced specifically for us and sold exclusively to us. We also use a custom-designed process to synthesize macromonomers, a key raw material needed in contact lens production, which are produced by a contract vendor for a negotiated price.

Marketing and Distribution

Contact lenses are considered medical devices by regulatory authorities and, therefore, are available only with a prescription from an eye-care professional in most countries. CIBA Vision lenses can be purchased from independent eye care professionals and optical chains. CIBA Vision's lens care products can be found in major drug, food and mass merchandising retail chains in the United States, Europe, Japan and elsewhere. In addition, mail order and Internet sales are becoming increasingly important channels in major markets worldwide.

Eyecare professionals are CIBA Vision's primary marketing focus. In addition, we have direct-to-consumer ("DTC") initiatives including free trials, coupons and bundling.

Competition

Contact Lenses

Growth in the contact lenses market is driven primarily by an increased demand for lenses and an increasingly varied product mix. As consumers move toward frequent replacement lenses, including

one-day disposable lenses, consumer demand for lenses is increasing. Additionally, the customer base is expanding with the development of new contact lens options, such as daily disposable, 30-night continuous wear, toric lenses for astigmatic patients and lenses to correct presbyopia, a condition prevalent among the "Baby Boom" generation. We are well-positioned in the contact lens market as the second-leading player on the basis of market share. With the acquisition of Wesley Jessen, we now have the broadest product portfolio of any competitor in the industry. Although the market has experienced the successful introduction of laser vision correction as an alternative to contact lenses, we have a number of products for consumers who are not candidates for laser correction such as teenagers and presbyopes. The colored lens technology acquired with Wesley Jessen also creates a strong combination with our CIBA Vision products that should prove attractive to teenagers and others. Our principal competitors in contact lenses are Bausch & Lomb and Johnson & Johnson.

Lens Care

We expect to increase our presence in the one-bottle market segment with our SOLO-care® lens care product and to maintain a leadership position in the peroxide category with AOSept Clear Care. Lens care, which is required by wearers of frequent replacement and conventional contact lenses, is a mature market and the products will continue to face competitive pressure due to the increasing preference for daily disposable and continuous wear lenses, which require little or no lens care.

CIBA Vision is a global leader in the peroxide lens care category with AOSept®, although this is a declining segment of the market. Market segment share is increasing in the growing one-bottle market segment with our SOLO-care® disinfection system. Our principal competitors in lens care are Alcon, Allergan and Bausch & Lomb.

Ophthalmic Surgical

The Ophthalmic Surgical market includes intra-ocular lenses and phaco equipment for cataracts, laser vision correction, surgical devices, surgical adjuncts and vitreo-retinal products. We are present in the cataract segment with our intra-ocular lens, MemoryLens®, which is the only pre-folded, intraocular lens on the market. We are the only competitor with a position in both the anterior and posterior phakic refractive lens market where we have acquired licenses. Phakic refractive lenses are used for patients requiring a high degree of correction. Our principal competitors in the ophthalmic surgical market are Alcon, Allergan, Bausch & Lomb, Pharmacia and Staar Surgical.

Research and Development

The research results of other Novartis affiliates provide CIBA Vision with new chemical compounds for future products and access to developments in biotechnology. These resources are complemented by CIBA Vision's internal research and development capabilities, licensing agreements and joint research and development partnerships with third parties (companies, individuals and universities). We invested CHF 98 million, CHF 150 million (inclusive of CHF 83 million for Ophthalmic Pharmaceuticals), and CHF 144 million (inclusive of CHF 80 million for Ophthalmic Pharmaceuticals) in research and development of eye care products in 2001, 2000, and 1999 respectively.

Regulation

Contact lenses, surgical devices and lens care products are regulated as medical devices in the United States, the EU and Japan. These jurisdictions each have risk-based classification systems that determine the type of submission or dossier required.

Medical devices in the United States are classified by the FDA into one of three classes: Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. All devices must receive pre-market approval by the FDA. There are two review procedures to gain this pre-market approval: a pre-market application ("PMA") and 510(k) submission. Under a PMA

the manufacturer must, with supporting evidence, prove the safety and effectiveness of the device. The FDA has 180 days to review a PMA. Certain products, however, may qualify for a submission authorized by Section 510(k) of the US Food Drug and Cosmetic Act, wherein the manufacturer gives the FDA a pre-market notification of the manufacturer's intention to commence marketing the product having established that it is substantially equivalent to another marketed product. The FDA has 90 days to review a 510(k) submission. In the United States, extended-wear lenses are deemed high risk and are therefore classified as Class III devices requiring a PMA. Ophthalmic surgical devices fall into both PMA or 510(k) categories depending on the availability of data from previously approved devices. Lens care products are Class II devices and generally qualify for 510(k) submission. The FDA may inspect all manufacturing facilities in order to ensure compliance with manufacturing requirements under its regulations.

The CE Mark, is required for all medical devices sold in the EU. The CE Mark is granted based on certification of compliance to the ISO standards for Quality System requirements and a review of product conformity to the essential requirements of the Medical Device Directive ("MDD"). Contact lenses, surgical devices and lens care products are evaluated according to the criteria of the MDD in order to determine risk for which essential requirements must be followed.

In Japan, contact lenses are categorized as medical devices and are subject to an approval process similar to that in the United States. Although there is an improvement in the willingness to accept foreign data and a movement toward harmonization of requirements, in order to enter the Japanese market, local clinical trials often are required and local protocols must then be observed. Lens care products for soft lenses take several years to gain approval due to the extensive amount of additional data and clinical testing required. Surgical devices are also categorized by risk level and a lengthy testing, review and approval process is required. Saline solutions for hard lenses are unregulated.

Intellectual Property

The majority of our products are protected by patents and trademarks. It is our policy to seek the broadest possible protection allowable under the law for significant product developments in all major markets. Patents may cover products *per se*, product formulations, processes, intermediate products and product uses.

ANIMAL HEALTH

The Animal Health business enhances and extends the life of companion animals and improves the health and productivity of farm animals. At December 31, 2001, the affiliates of Animal Health employed 1,997 people and had sales of CHF 962 million which represented 3% of Group's sales.

Represented by affiliates in approximately 40 countries, Animal Health researches, develops, manufactures and markets a wide variety of products for both companion and farm animals including farmed fish. The companion animal segment and the farm animal segment (including Aquaculture) each account for 50% of our total Animal Health sales. Products include parasiticides in companion and farm animals, antibacterials, vaccines and veterinary pharmaceuticals. Our Animal Health business has a dedicated research team and benefits from synergies in research and development with other Novartis businesses, most notably, Pharmaceuticals.

We acquired Grand Laboratories Inc. and ImmTech Biologics Inc. in the United States in January 2002 for a minimum of CHF 160 million. These businesses specialize in the development, manufacture and marketing of vaccine products for cattle and pigs. It is anticipated that through these acquisitions we can improve our presence in the vaccines business as well as establish our presence in the US farm animal business. The two businesses generated combined revenues of USD 33 million in 2001.

Recently Launched Products

Product	Description	Registration/Launch Status
Capstar®	Fast-acting oral flea control for dogs and cats	2001 launches in US, Canada and UK, already registered and launched in Australia, New Zealand, Switzerland, Brazil and South Africa
Program® Plus . .	Flea and intestinal worm prevention for dogs and cats	Registered and launched in UK, Spain, Portugal and Germany
Fortekor®	Claim extension for chronic renal insufficiency in cats	Claim extension registered and launched in Europe
Fasimec®	Parasite control for farm animals	Registered and launched for cattle in Australia
Clik®	All-season protection against blowflies in sheep	2001 launch in UK, already registered and launched in New Zealand and Australia
Endex®	Parasite control for farm animals	2001 launch in Switzerland, registered and launched in 12 countries worldwide

Key Marketed Products

Key products for pets (dogs and cats) include Sentinel®, Interceptor® and Program® for the prevention of fleas, heartworm and intestinal worms; and Fortekor® for the treatment of heart failure in dogs and chronic renal insufficiency in cats. Key products for farm animals include Tiamutin® (antimicrobials) to treat bacterial infections in pigs and poultry, Vetrizin® and Clik® against blowfly in sheep; Fasinex® and Endex® for the treatment and control of liver fluke and gastro-intestinal worms in cattle and sheep. Other important products are the farm fly control range as well as vaccines for farm animals and farmed fish.

Products in Development

Novartis Animal Health research and development activities focus on the area of antiparasitics for companion and farm animals. We also develop veterinary pharmaceuticals for pets in new indication areas such as dermatitis, as well as vaccines for farm animals and farmed fish.